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Der Präsident des Europäischen Patentamts;

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Hand-held electronically controlled injection device for injecting liquid medications

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HAND-HELD ELECTRONICALLY CONTROLLED INJECTION DEVICE FOR INJECTING LIQUID MEDICATIONS

The present invention relates to a hand-held, electronically controlled injection device for injecting liquid medications, and in particular of the type for performing subcutaneous injections fully automatically.

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As is known, certain types of diseases, such as diabetes, call for injecting medications, such as insulin, several times a day, and the medication dosage to be injected may vary from one patient to another, and, for the same patient, during the day and from one day to another.

Over the past few years, therefore, electronically controlled injection devices have been devised and widely used to permit self-injection of medications in the required doses.

Patent Application US-A-2002/0133113 describes one such injection device substantially comprising a handheld housing, which houses a cartridge containing the liquid medication for injection, and defines, on a contact surface for contacting the patient's skin, a through opening by which to fit a disposable needle to one end of the cartridge. The injection device also comprises an electromechanical actuator assembly, which is activated selectively to slide a plunger hermetically inside the cartridge body and deliver the liquid medication through the needle into the patient's skin.

Operation of the injection device is controlled by a programmable microprocessor, which receives signals from various switches and buttons — e.g. one or more medication dose selection buttons and an injection start button — and generates signals by which to control the actuator assembly according to a program stored in the microprocessor.

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The injection device described therefore provides for selecting each medication dose for injection, and delivering the dose automatically.

functionally valid, the above type Though room device still leaves for further injection More specifically, a need is felt improvement. solutions designed to further reduce the amount of human intervention required, and to further safeguard users, with no medical experience, in preparing and selfinjecting medications.

It is an object of the present invention to provide an electronically controlled injection device for injecting liquid medications, designed to meet the above requirement, and which in particular provides for preparing and performing subcutaneous injections fully automatically.

According to the present invention, there is provided a hand-held, electronically controlled injection device for injecting preset doses of liquid medications, comprising a housing which is adapted for receiving a medication container containing the liquid medication,

and has a contact surface for contacting a patient's skin, characterized by comprising first actuator means for moving said medication container within said housing to and from said contact surface.

A preferred, non-limiting embodiment of the present invention will be described by way of example with reference to the accompanying drawings, in which:

Figure 1 shows a front view of an injection device in accordance with the present invention;

Figures 2 and 3 show, with parts removed for clarity, larger-scale views in perspective, from opposite sides, of the internal components of the Figure 1 injection device;

Figures 4, 5, 6, 7 and 8 show a portion of the 15 Figure 1 injection device illustrating assembly of a disposable needle;

Figures 9, 10 and 11 are similar to Figures 4-8, and illustrate removal of the needle from the injection device according to the invention;

20 Figure 12 shows a block diagram illustrating operation of a control unit for controlling the Figure 1 injection device.

Number 1 in Figure 1 indicates as a whole a hand-held, electronically controlled injection device for injecting liquid medications, and in particular for performing subcutaneous injections fully automatically.

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Injection device 1 substantially comprises a handheld housing 2 defining a seat 3 for receiving a cartridge 4 containing the liquid medication; an injection driving unit 5 (Figures 2 and 3) housed inside housing 2 and selectively activated to cooperate with cartridge 4 and inject the patient with a preset dose of medication; and an electronic control unit 6 (Figure 12) – in the example shown, a microprocessor – also housable inside housing 2 to control operation of injection driving unit 5.

More specifically, housing 2, in the example shown,

is of thin prismatic shape, and comprises a front wall 7

fitted with an LCD display 8 and set-up buttons 9

(operation of which is described in detail later on); a

rear wall 10; two sides 11, 12; a bottom wall 15 defining

a contact surface 16 for contacting the patient's skin;

and a top wall 17 fitted with an injection start button

18, as explained in detail later on.

As shown in Figure 1, one of the sides (11) of housing 2 has a door 19 hinged at the bottom about an axis perpendicular to front wall 7 and rear wall 10, and which opens outwards to permit insertion of cartridge 4 inside seat 3.

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In the example shown, seat 3 for receiving cartridge 4 has an axis A perpendicular to bottom wall 15 and top wall 17, and is formed close to side 11.

Close to the opposite side 12, housing 2 also defines a seat 20 (Figures 1 to 3) having an axis parallel to axis A, and for receiving one or more batteries 21 for electrically powering injection device

1, and which are inserted through a further door 22 formed in bottom wall 15.

As shown in Figures 1 to 11, cartridge 4 is defined by a hollow cylindrical body 23 containing a predetermined quantity of liquid medication, and having a closed, small-section end 24, through which a commonly marketed disposable needle 25 is insertable in known manner, and an open opposite end 26 engaged in fluidtight manner by a disk-shaped member or plunger 27, which is activated by injection driving unit 5 to slide inside body 23 and deliver the medication through needle 25.

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Cartridge 4 is inserted inside housing 2 with end 24 for needle 25 facing bottom wall 15 and, therefore, contact surface 16 for contacting the patient's skin; and bottom wall 15 has a through opening 30, of axis A, by which to fit and remove needle 25 to/from cartridge 4, and through which needle 25 is ejected to inject the skin.

cartridge 4 has known external markings (not shown),
20 e.g. bar codes, notches, conducting material in a
predetermined pattern, etc., by which to determine the
presence of cartridge 4 inside housing 2, and to obtain
information relating to the medication, such as
composition, concentration, expiry date, etc. Another
25 possibility for identifying cartridge 4 is to use a radio
frequency identification system.

As shown clearly in Figures 4 to 6, needle 25 is supplied in a protective needle housing 31 to prevent

injury to the user, and defines, with needle housing 31, a needle assembly 32.

More specifically, needle 25 is fixed to and projects from a plastic needle support 33 which fits onto end 24 of body 23 of cartridge 4.

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As is known, needle 25 comprises a front portion 34 (at the bottom in Figures 2 to 11) for piercing the patient's skin and which projects from needle support 33; and a rear end 35 (at the top in Figures 4 to 11) enclosed in needle support 33 and which fits through end 24 of body 23 of cartridge 4. More specifically, needle support 33 comprises a number of elastic flanges 36 surrounding rear end 35 of needle 25, and which engage end 24 of body 23 of cartridge 4 as described in detail later on.

As an alternative not shown, the reverse arrangement of the engagement between the needle support and the cartridge end is also possible; in this latter case, the cartridge end may be provided with elastic flanges engaging the needle support. This further embodiment has the advantage that the needle support need not be specially designed with elastic flanges, but rather a standard commercially available needle assembly may be used (even one with screw threads, which is a common commercially available version).

Needle housing 31 is defined by a cylindrical, cupshaped body housing front portion 34 of needle 25, and the open end of which is fitted to needle support 33. In the example shown, needle assembly 32 also comprises an inner needle housing 37 covering front portion 34 of needle 25.

With reference to Figures 2 and 3, injection driving unit 5 comprises an electromechanical actuator assembly 40, which is selectively activated to act on plunger 27 of cartridge 4 and move it, inside body 23 of cartridge 4, towards end 24 to deliver the liquid medication through needle 25.

10 According to an important aspect of the present invention, injection driving unit 5 comprises a further electromechanical actuator assembly 41 for moving cartridge 4, inside housing 2 and along axis A, to and from contact surface 16 to automatically fit and remove 15 needle 25 to/from cartridge 4, and to insert needle 25 inside the patient's skim at a predetermined speed.

More specifically, cartridge 4 is fitted to a supporting sleeve 42 which slides axially inside seat 3 of housing 2.

As shown in Figures 2 and 3, supporting sleeve 42 is open, not only at opposite axial ends, but also on the side facing door 19 to permit insertion of cartridge 4.

More specifically, supporting sleeve 42 comprises a small-section bottom end portion 38 for receiving end 24 of cartridge 4, and which, when fitting needle 25 to cartridge 4, is engaged by elastic flanges 36 of needle support 33. End portion 38 also defines an annular shoulder 39 with the rest of supporting sleeve 42.

Actuator assembly 40 comprises an electric gear motor 43; a push member 44 which acts on plunger 27 of cartridge 4 to move it, inside body 23 of cartridge 4, towards end 24; and a transmission 45 for converting the rotation generated by gear motor 43 into translation of push member 44.

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More specifically (Figure 2), transmission 45 substantially comprises a pinion 46 fitted to the output member of gear motor 43; a screw assembly 47 connected to push member 44; and an intermediate gear 48 having external teeth meshing with pinion 46, and internal teeth engaging a leadscrew 49 of screw assembly 47.

More specifically, leadscrew 49 is fitted to housing 2 to rotate but not translate axially; and screw assembly 47 also comprises a nut screw 50 fitted to leadscrew 49, integral with push member 44, and fitted to housing 2 to translate along, but not rotate with respect to, leadscrew 49.

Push member 44 is advantageously defined by the core of a known Bowden-type flexible cable 51, the sheath 52 of which has a portion fixed to housing 2, e.g. to top wall 17.

Actuator assembly 41 comprises an electric gear motor 53; a slide 54 integral with supporting sleeve 42 of cartridge 4 and movable parallel to axis A; and a transmission 55 for converting the rotation generated by gear motor 53 into translation of slide 54.

More specifically (Figure 3), slide 54 is defined by

a nut screw projecting laterally from supporting sleeve 42 and fitted to housing 2 to translate along, but not rotate with respect to, an axis parallel to axis A. Transmission 55 comprises a pinion 56 fitted to the output member of gear motor 53; a leadscrew 57 connected to slide 54 and fitted to housing 2 to rotate about, but not translate along, its own axis; and an intermediate gear 58 having external teeth meshing with pinion 56, and internal teeth engaging leadscrew 57.

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1 also comprises two or more retaining elements 60 extending about seat 3 to keep needle assembly 32 fitted to cartridge 4 in a predetermined position (Figure 5), in which needle assembly 32 projects along axis A from 15 bottom wall 15 of housing 2, and the portion having needle support 33 engages opening 30 in wall 15.

More specifically, retaining elements 60 are defined by levers extending parallel to axis A and having top ends 61 hinged to a structural portion of housing 2, and free bottom ends having locking flanges 62. More specifically, locking flanges 62 are located at opening 30, and extend perpendicular to axis A and inwards of opening 30.

Retaining elements 60 are loaded elastically inwards
25 of seat 3 to assume a lock configuration (Figures 5, 6,
10 and 11), and are parted into a release configuration
(Figures 4, 7, 8 and 9) by respective cam profiles 63
interacting with a contoured annular projection 64 on

supporting sleeve 42, as supporting sleeve 42 moves along axis A.

More specifically, supporting sleeve 42 and, with it, cartridge 4 are movable jointly by actuator assembly 41 in opposite directions along axis A to assume three distinct positions, namely:

- a top limit position (Figures 4 and 7) in which cartridge 4 is loaded and any automatic operation of injection device 1 (in this case, assembling and removing needle 25, and injecting the patient with medication) starts and ends;

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- a bottom limit position (Figures 10 and 11) in which needle 25 is removed from cartridge 4; and
- an operating position (Figure 6), close to the bottom limit position, in which the liquid medication is delivered through the patient's skin, and needle 25 is connected to cartridge 4.

As shown in Figures 4 to 11, the cam profile 63 of each retaining element 60 and the projection 64 on sleeve support 42 are in the form of complementary ramps and designed to cooperate mutually to part retaining elements 60 in and close to the top limit position of supporting sleeve 42, and to detach from each other, leaving retaining elements 60 subjected solely to the elastic return force towards axis A, in the other positions assumed by supporting sleeve 42 during its movement.

As shown in Figures 5 and 6, in the lock configuration, locking flanges 62 of retaining elements

60 cooperate with an outer rib 65, formed at the open end of needle housing 31, to retain needle assembly 32 inside opening 30 in bottom wall 15 as supporting sleeve 42 moves into the operating position, so that end portion 38 of supporting sleeve 42 fits inside the elastic flanges of needle support 33, and the rear end 35 of needle 25 is inserted inside end 24 of cartridge 4.

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As supporting sleeve 42 moves subsequently from the operating position to the top limit position, locking flanges 62 of retaining elements 60, still in the lock configuration, press on needle housing 31 to prevent it following needle 25, needle support 33 and inner needle housing 37 moving together with supporting sleeve 42, so that needle 25 and needle support 33 can be connected to cartridge 4 and withdrawn from needle housing 31 automatically.

In the bottom limit position of supporting sleeve 42 (Figures 10 and 11), locking flanges 62 of retaining elements engage the gap between 60 shoulder supporting sleeve 42 and the rear end of needle support 33 to arrest needle support 33 as supporting sleeve 42 subsequently moves into the top limit position, so that needle 25 and needle support 33 are withdrawn automatically from cartridge 4 after use.

With reference to Figure 12, control unit 6 receives a number of signals from various detecting elements and buttons on injection device 1, and supplies control signals for gear motors 43, 53 and display 8, according

to a program stored in control unit 6 itself.

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More specifically, control unit 6 receives the following signals:

- signals S1 from sensors 66 (e.g. optical, electrical, radio-frequency, infra-red, etc.) facing seat 3 and for detecting the markings on cartridge 4;
- a signal S2 from a presence sensor 67, e.g. a contact switch, located at opening 30 in bottom wall 15 and for determining engagement of the opening by an outer body of predetermined diameter, e.g. needle housing 31;
- a signal S3 from a skin sensor 68 located on bottom wall 15 of housing 2 and for determining contact with the patient's skin;
- signals S4 from set-up buttons 9, by which to select, for example, the dose for injection, the speed at which needle 25 penetrates the patient's skin, medication delivery speed, etc; and
  - a signal S5 from injection start button 18.

On the basis of the incoming signals, control unit 6 supplies signals C1 and C2 for controlling respective gear motors 43, 53 in both rotation directions, and a signal C3 for controlling display 8.

control unit 6 has its own internal memory 70 (shown externally for the sake of simplicity) which stores the action program of control unit 6 and the doses and timing of the injections performed, so as to inform the patient and/or doctor of these and the number of doses left in cartridge 4. The doctor can therefore check patient

compliance.

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Injection device 1 is also provided with an interface (known per se and not shown), e.g. a USB port, a Bluetooth communication, a infra-red port, etc., that allows information exchange with a computer for data analysis.

Programming of injection device 1 may also be possible (for example by uploading from a computer), which may be useful for clinic trials (for example, permitting injection only of certain amounts and at certain times/intervals).

Operation of injection device 1 will be described as of the Figure 4 configuration, in which supporting sleeve 42 has no needle 25 and is set to the top limit position, and cartridge 4 has been inserted through door 19 into seat 3 of housing 2 and connected to supporting sleeve 42.

Assembly of needle 25 to cartridge 4 is controlled fully automatically by control unit 6, and is activated by simply inserting needle assembly 32, by the open end of needle housing 31, inside opening 30 in bottom wall 15 of housing 2. Insertion of the needle assembly is immediately detected by presence sensor 67, so that control unit 6 activates gear motor 53 in the direction designed, via transmission 55 and slide 54, to move supporting sleeve 42 into the operating position.

As a result of the above movement of supporting sleeve 42, projection 64 is detached from cam profiles

63, so that retaining elements 60 move inwards of opening 30, and locking flanges 62 close onto needle housing 31 to lock it in position partly engaging opening 30 (Figure 5).

Needle assembly 32 can be inserted inside opening 30 either by hand or using an adapter indicated as a whole by 71 in Figures 4 to 10.

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More specifically, adapter 71 is double-cup-shaped, and comprises opposite portions 72, 73 of different diameters defining respective cavities open on opposite sides and for housing needle housing 31 and inner needle housing 37 respectively. The larger-section portion 72 also houses a cylindrical slip sleeve 76 defining the actual seat for needle housing 31, and the function of which is explained later on; and the smaller-section portion 73 is provided internally, close to the open end, with an inner rib 74 which presses on inner needle housing 37 to remove it from the assembly defined by needle 25 and needle support 33.

As supporting sleeve 42 reaches the operating position (Figure 6), end portion 38 is inserted between elastic flanges 36 and connected to needle support 33, and the rear end 35 of needle 25 is inserted inside end 24 of cartridge 4.

At this point, the rotation direction of gear motor 53 is inverted, and supporting sleeve 42 moves from the operating position to the top limit position. As it does so, needle support 33, needle 25 and, with it, inner

needle housing 37 are withdrawn axially from needle housing 31 locked partly engaging opening 30 by retaining elements 60.

Close to the top limit position, projection 64 on supporting sleeve 42 interacts with cam profiles 63 of retaining elements 60 to part retaining elements 60, so that locking flanges 62 move outwards of opening 30 to release needle housing 31 (Figure 7).

Once supporting sleeve 42 reaches the top limit position, adapter 71 can be inserted through opening 30 into seat 3 by portion 73, the cavity of which is thus engaged by inner needle housing 37. Given its smaller diameter, insertion of portion 73 is not detected by presence sensor 67. When adapter 71 is extracted from opening 30, inner needle housing 37 is removed from needle 25 (Figure 8).

Consent to start the actual injection is given by surface 16 contacting the patient's skin and so activating skin sensor 68.

When start button 18 is pressed, gear motor 53 is first activated and, via transmission 55, moves supporting sleeve 42 back into the operating position, so that needle 25 penetrates the patient's skin. Gear motor 43 is then activated and, via transmission 45 and push member 44, acts on plunger 27 of cartridge 4 to slide it towards end 24 and deliver a predetermined dose of liquid medication.

Before the injection is performed, the dose to be

injected, the speed at which needle 25 penetrates the patient's skin, the speed at which the liquid medication is delivered and the injection depth can be selected using set-up buttons 9 and displayed on display 8.

Once the injection is completed, supporting sleeve 42 moves back into the top limit position.

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Needle 25 can be removed from cartridge 4 fully automatically using adapter 71 (Figures 9 and 10), or directly using a needle box 75 (Figure 11), e.g. of the type known by the trade name "SHARPS BOX".

More specifically, when using adapter 71 used to remove needle housing 31 and inner needle housing 37 (Figures 9 and 10), slip sleeve 76 must first be extracted from portion 72 to rest axially on rib 65 of needle housing 31.

At this point, needle housing 31 and the extracted part of slip sleeve 76 are inserted through opening 30 in housing 2 to activate presence sensor 67, so that control unit 6 activates gear motor 53 to move supporting sleeve 42 from the top limit position to the bottom limit position.

As cam profiles 63 are detached from projection 64 on supporting sleeve 42, retaining elements 60 are prevented from moving into the lock configuration by locking flanges 62 resting on slip sleeve 76 of adapter 71 (Figure 9).

As supporting sleeve 42 reaches the bottom limit position (Figure 10), however, locking flanges 62 of

retaining elements 60 click inside the gap between shoulder 39 on supporting sleeve 42 and the top axial end of needle support 33.

At this point, the rotation direction of gear motor 5 53 is inverted, and supporting sleeve 42 moves into the top limit position. As it does so, needle support 33 and needle 25 remain in the position in which they are retained by locking flanges 62, and are thus withdrawn axially from supporting sleeve 42 and cartridge 4.

As supporting sleeve 42 reaches the top limit position, retaining elements 60 are again parted, and injection device 1 is ready to be fitted with another needle 25 for the next injection.

When using needle box 75 (Figure 11), this is simply inserted by the mouth end inside opening 30 to activate presence sensor 67 and automatically remove needle 25 from cartridge 4 in exactly the same way as described relative to adapter 71.

The advantages of injection device 1 according to 20 the present invention will be clear from the foregoing description.

In particular, by permitting control of the movement of cartridge 4 to and from contact surface 16, injection device 1 provides for fully automatically fitting and removing needle 25 to/from cartridge 4, and controlling the speed at which needle 25 penetrates the patient's skin.

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In other words, when the actual injection is

performed, it is possible to set not only the medication dose and the speed at which the dose is delivered, but also the speed at which needle 25 is ejected from housing 2, and therefore skin penetration speed.

Clearly, changes may be made to injection device 1 as described and illustrated herein without, however, departing from the scope of the accompanying Claims.

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In particular, the movement of cartridge 4 and delivery of the medication contained in cartridge 4 may be controlled using a single gear motor, which may, for example, by means of a transmission similar to those described, control axial displacement of the core of a Bowden-type flexible cable acting on plunger 27 of cartridge 4; and releasable locking means may be provided for selectively making plunger 27 and body 23 of cartridge 4 integral with each other, so that, when the locking means are activated, cartridge 4 is moved to and from contact surface 16, and, when the locking means are released, plunger 27 slides inside body 23 of cartridge 4 to deliver the medication.

Moreover, the function of retaining needle assembly 32 in a predetermined position for fitting to cartridge 4 may be performed by a tab or tabs actuated by the needle assembly itself.

25 Furthermore, injection device 1 can be used, in the same way as disclosed, with other types of medication containers, such as a syringe.

## CLAIMS

1) A hand-held, electronically controlled injection device (1)for injecting preset doses of liquid medications, comprising a housing (2) which is adapted for receiving a medication container (4) containing the liquid medication, and has a contact surface (16) contacting a patient's skin, characterized by comprising first actuator means (41) for moving said medication container (4) within said housing (2) to and from said contact surface (16).

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- 2) A device as claimed in Claim 1, characterized in that said contact surface (16) of said housing comprises a through opening (30) for receiving a needle assembly (32) comprising a needle (25) and at least one needle housing (31) fitted to said needle (25); and by comprising releasable retaining means (60) for locking said needle housing (31) in a predetermined position engaging said opening (30), both during displacement of said medication container (4) towards said contact surface (16) from a first operating position withdrawn inside said housing (2) to a second operating position said needle (25), to and during displacement of said medication container (4) from said second to said first operating position to automatic withdrawal of said needle (25) from said needle housing (31).
  - 3) A device as claimed in Claim 2, characterized by

comprising presence sensor means (67) which generate a presence signal (S2) to activate said first actuator means (41) upon said needle housing (31) engaging said opening (30).

- 5 4) device claimed in Claim 2 as 3, characterized in that said retaining means comprise at least one locking lever (60) movable between a lock configuration, in which a respective work portion (62) projects inside said opening (30) to interact with said 10 needle housing (31), and a release configuration, which said work portion (62) is located outside said opening (30).
  - 5) A device as claimed in Claim 4, characterized in that said locking lever (60) is loaded elastically into the lock configuration; and in that push means (63, 64) are provided to set said locking lever (60) to said release configuration at least in said first operating position of said medication container (4).

- 6) A device as claimed in Claim 5, characterized in 20 that said push means comprise cam means (63, 64) interposed between said locking lever (60) and a support (42) for supporting said medication container (4) and which is movable to and from said contact surface (16).
- 7) A device as claimed in any one of Claims 2 to 6,
  25 characterized by comprising removing means (60, 62) for
  removing said needle (25) from said medication container
  (4); said removing means comprising stop means (60, 62)
  which are activated selectively in a third operating

position of said medication container (4), close to said second operating position, to lock said needle (25) and disconnect said needle from said medication container (4) as said medication container (4) moves into said first operating position.

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- 8) A device as claimed in Claim 7, characterized in that said third operating position is located on the opposite side of said second operating position with respect to said first operating position in the travelling direction of said medication container (4).
- 9) A device as claimed in Claim 7 or 8, for connection to a needle assembly (32) comprising a needle support (33) supporting said needle (25) in projecting manner and connectable to one end (24) of said medication container (4), characterized in that, in said third operating position of said medication container (4), said work portion (62) of said locking lever (60) is interposable between said medication container (4) and said needle support (33) to define said stop means.
- 20 10) A device as claimed in any one of the foregoing Claims, characterized by comprising second actuator means (40) which are activated selectively to force the liquid medication contained in said medication container (4) through the patient's skin.
- 25 11) A device as claimed in Claim 10, characterized by comprising injection control button means (18), said button means (18) successively activating said first actuator means (41) to move the assembly defined by the

medication container (4) and needle (25) from the first to the second operating position so that the needle (25) penetrates the patient's skin, and said second actuator means (40) to deliver through the patient's skin a preset dose of liquid medication contained in said medication container (4).

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- 12) A device as claimed in Claim 11, characterized by comprising skin sensor means (68) which generate a consent signal (S3) to activate said button means (18) upon interaction between said contact surface (16) and the patient's skin.
- claimed in 13) A device as Claim 11 12, characterized by comprising selecting means (9) for selecting the speed at which said medication container 15 (4) moves towards said contact surface (16) at least as said needle (25) penetrates the patient's skin, and for setting the dose of liquid medication to be injected into the patient.

## ABSTRACT

There is described a hand-held, electronically controlled injection device (1) for injecting preset doses of liquid medications, having a housing (2) receiving a cartridge (4) containing the liquid medication and having a contact surface (16) contacting a patient's skin; and actuator means (41) for moving the cartridge (4) within the housing (2) to and from the contact surface (16). (Figure 3)

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